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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/752,643	01/08/2004	Tatsumasa Mae	12218/29	4212
23838	7590	07/05/2005	EXAMINER	
KENYON & KENYON 1500 K STREET NW SUITE 700 WASHINGTON, DC 20005			COE, SUSAN D	
			ART UNIT	PAPER NUMBER
			1655	

DATE MAILED: 07/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/752,643	MAE ET AL.	
	Examiner	Art Unit	
	Susan D. Coe	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 9-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/8/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Claims 9-22 are currently pending.
2. Applicant's response to the restriction requirement filed June 13, 2005 is acknowledged.

The restriction requirement is hereby withdrawn in view of applicant's arguments and applicant's disclosures in the specification.

3. Claims 9-22 are examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 11-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating Insulin Resistance Syndrome, diabetes mellitus, and obesity, does not reasonably provide enablement for prevention of these disorders. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

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Applicant's claims are broadly drawn to composition that is able to prevent Insulin Resistance Syndrome, diabetes mellitus, and obesity. In order to be enabled for prevention of a condition, applicant must demonstrate that the invention is able to prevent the condition in each and every instance of that condition. Applicant's specification does not set forth any evidence that the claimed product is able to prevent Insulin Resistance Syndrome, diabetes mellitus, and obesity for all potential causes of Insulin Resistance Syndrome, diabetes mellitus, and obesity. The specification only demonstrates that the claimed composition is able to lower body fat and lower blood glucose (see Examples 3 and 4). In addition, it is well known in the art that diabetes and obesity are difficult, if not impossible, to prevent. Thus, a person of ordinary skill in the art would be forced to experiment unduly in order to determine if applicant's invention actually function as claimed. Therefore, the claims are not considered enabled for the prevention of Insulin Resistance Syndrome, diabetes mellitus, and obesity.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 9-12, 14, 15, 17, 18, 20 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Japanese Pat. Pub. No. 11-246399 (English translation provided).

JP '399 teaches a method of treating diabetes mellitus by administering curcumin, demethoxycurcumin and bisdemethoxycurcumin (curcuminoids). The curcumin composition is

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formulated as a pharmaceutical, food or drink and is administered to a mouse (see paragraphs 9, 12, 15 and Examples).

The reference does not specifically teach that the method of treating diabetes also treats Insulin Resistance Syndrome or activates a peroxisome proliferator-activated receptor. However, according to applicant's specification, diabetes is a type of Insulin Resistance Syndrome (see paragraph 1). Thus, treating diabetes as taught by the reference would also treat Insulin Resistance Syndrome according to the definition of the syndrome in applicant's specification. In addition, the activation of peroxisome proliferator-activated receptor would inherently have to occur in the method taught by the reference. This is because the same disease as claimed is treated with the same composition as claimed. Thus, the mechanism of action, i.e. activation of the peroxisome proliferator-activated receptor, must be the same if applicant's invention functions as claimed.

6. Claims 9-11, 13, 14, 16, 17, 19, 20, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/22728.

WO '728 teaches a method of treating obesity by administering a composition comprising curcumin and curcuminoids. The composition is formulated as a pharmaceutical, liquid, or is added to food. The composition is administered to hamsters (see pages 12, 13, 16, 23, figure 8, and claim 6).

The reference does not specifically teach that the method of treating obesity also treats Insulin Resistance Syndrome or activates a peroxisome proliferator-activated receptor. However, according to applicant's specification, obesity is a type of Insulin Resistance Syndrome (see paragraph 1). Thus, treating obesity as taught by the reference would also treat

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Insulin Resistance Syndrome according to the definition of the syndrome in applicant's specification. In addition, the activation of peroxisome proliferator-activated receptor would inherently have to occur in the method taught by the reference. This is because the same disease as claimed is treated with the same composition as claimed. Thus, the mechanism of action, i.e. activation of the peroxisome proliferator-activated receptor, must be the same if applicant's invention functions as claimed.

7. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding can be directed to the receptionist whose telephone number is (571) 272-1600.

Susan D. Coe
6-24-05

Susan D. Coe
Primary Examiner
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